

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application	)	<u>PATENT APPLICATION</u>
	)	
Inventor(s): Nathaniel E. David	)	
	)	Art Unit: Unassigned
Application No.: Unassigned	)	
	)	Examiner: Unassigned
Filed: Herewith	)	
	)	
Title: Compositions And Methods To Increase	)	
The Effect Of A Neurotoxin Treatment	)	

Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97**

Sir:

Listed below or on an attached Form PTO-1449 is information known to applicant(s). A copy of each listed publication and U.S. and foreign patent, except for pending U.S. applications, is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. If form PTO-1449 is enclosed, the Examiner is requested to initial and return it in accordance with MPEP §609.

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56.

- ☒ This statement qualifies under 37 C.F.R. §1.97, subsection (b) because (check all that apply):
- ☒ (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)  
-- OR --
- ☐ (2) It is being filed within 3 months of entry of a national stage  
-- OR --
- ☐ (3) It is being filed before the mail date of the first Office Action on the merits  
-- OR --
- ☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.
- ☐ 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:
- ☐ a certification as specified in §1.97(e) is provided below; **or**
- ☐ a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☐ 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:
- A. a certification as specified in §1.97(e) is completed below; and
- B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; **and**
- C. a fee of \$130.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- ☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:
- ☐ In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application (Serial No. \_\_\_\_\_), copies are not enclosed herewith.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

- ☐ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).
- ☒ There are no listed references that are not in the English language.
- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.
- ☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.
- ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No. 29117.705.201).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: 4-26-04

By:   
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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application No.	Unassigned
				Filing Date	Herewith
				First Named Inventor	Nathaniel E. David
				Art Unit	Unassigned
				Examiner Name	Unassigned
Sheet	1	Of	1	Attorney Docket No. 29117.705.201	

OTHER PRIOR ART – NON PATENT RELATED DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher city and/or country where published	T <sup>2</sup>
		ADAMS, J. P., et al., "U0126: An Effective Inhibitor of MAPK Activation in Neuronal Tissue," <i>Neural Notes</i> , (1999) Vol. V, Issue 1, pages 14-16.	
		ALETSEE, C. et al., "Ras/MEK But Not p38 Signaling Mediates NT-3-Induced Neurite Extension From Spiral Ganglion Neurons," <i>Journal of the Association for Research In Otolaryngology</i> , (2001) pages 377-387.	
		BILLANTE, C. et al., "Comparison of Neuromuscular Blockade And Recovery With Botulinum Toxins A and F," <i>Muscle &amp; Nerve</i> , (2002) Vol. 26, pages 395-403.	
		"Botox – Frequently Asked Questions," <a href="http://www.botox.com/site/professionals">www.botox.com/site/professionals</a> , printed from the website on January 15, 2004, pages 1-5.	
		KATO-STANKIEWICZ, J. et al., "Inhibitors of Ras/Raf-1 Interaction Identified by two-Hybrid Screening Revert Ras-Dependent Transformation Phenotypes in Human Cancer Cells," <i>Proceedings of the National Academy Sciences</i> , (2002) Vol. 99, No. 22, pages 14398-14403.	
		MARKUS, A. et al., "Raf and Akt Mediate Distinct Aspects of Sensory Axon Growth," <i>Neuron</i> , (2002) Vol. 35, pages 65-76.	
		MIURA, T. et al., "Partial Functional Recovery of Paraplegic Rat by Adenovirus-Mediated Gene Delivery of Constitutively Active MEK1," <i>Experimental Neurology</i> (2000) Vol. 166, pages 115-126.	
		SJÖGREEN, B. et al., "Mitogen Activated Protein Kinase Inhibition by PD98059 Blocks Nerve Growth Factor Stimulated Axonal Outgrowth From Adult Mouse Dorsal Root Ganglia <i>In Vitro</i> ," <i>Neuroscience</i> , (2000) Vol. 100, No. 2, pages 407-416.	
		VAUDRY, D. et al., "Signaling Pathways For PC12 Cell Differentiation: Making The Right Connection," <i>Science</i> , (2002) Vol. 296, pages 1648-1649.	
		WILLIAMS, T. et al., "Lead Enhances NGF-Induced Neurite Outgrowth in PC12 Cells by Potentiating ERK/MAPK Activation," <i>NeuroToxicology</i> , (2000) Vol. 21, No. 6, pages 1081-1090.	
		ZENG, J. et al., "Design of Inhibitors of Ras-Raf Interaction Using a Computational combinatorial Algorithm," <i>Protein Engineering Design and Selection</i> , (2001) Vol. 14, No. 1, printed from website <a href="http://www.peds.oupjournals.org/cgi">www.peds.oupjournals.org/cgi</a> on January 21, 2004, pages 1-14.	
EXAMINER SIGNATURE		DATE CONSIDERED	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.